



**The Obesity Society
Statement at the FDA Panel 7/15/10**

Obesity is a chronic, relapsing, neurochemical disease and, as the root cause of type 2 diabetes and other medical comorbidities, is a major contributor to the public health burden in the United States. Overweight and obesity is the second leading cause of preventable death in the United States.¹ While a few recent studies have suggested that obesity rates may have begun to level off, still, 2/3 of Americans are overweight or obese and more than 1/3 are obese. Moreover, the burden of obesity is disproportionately borne by women and minorities.

The Obesity Society is the leading organization in the U.S. dedicated to studying the causes, consequences, prevention, and treatment of obesity. The Obesity Society endorses that to reduce the burden of the obesity epidemic, a multifaceted approach is needed. Such an approach should combine clinical, public health, and policy approaches to the prevention and treatment of obesity. Pharmacotherapy can be a useful tool within a "toolbox" of clinical approaches to treatment. We support the use of weight loss medications in appropriately selected patients. The choice to use medication is an individual decision that must be undertaken between clinicians and their patients. Our position is in agreement with guidelines from medical professional societies such as the American Medical Association and the American College of Physicians,²⁻⁴ as well as treatment recommendations from the National Institutes of Health.⁵

Because of its chronic nature, cure of obesity is rare, but palliation is a realistic clinical goal. Weight loss occurs with most treatments, and, except for surgery or very-low-calorie diets, it is usually slow (0.5-1.0 kg/week). Recidivism, or regain of body weight, is common after a weight loss program is terminated. In contrast to the relatively slow rate of weight loss, weight regain may be rapid. A regain in weight after termination of drug treatment is often ascribed to a failure of the drugs or other treatment. A more appropriate interpretation is that treatments do not work if they are not implemented and medications do not work if not taken. This is true of medications for the treatment of obesity, just as it is for medications used to treat hypertension, diabetes, heart disease, or asthma. Because obesity is a chronic disease and obesity medications must be taken over the long term, safety of these agents is paramount.

The Obesity Society supports the following specific recommendations regarding the use of pharmacotherapy:

- All prescription medications for weight loss should be subjected to large clinical trials, with enough participants to assess safety.⁶

- Weight loss agents should be tested for efficacy in subgroups that include women and men, as well as ethnic minorities with disproportionate rates of obesity (e.g., African-Americans, Latinos).
- The use of pharmacotherapy in clinical practice should follow established guidelines.⁵ Specifically, weight loss drugs should be prescribed only to patients with obesity (BMI ≥ 30 kg/m²) or to overweight patients (BMI ≥ 27 kg/m²) with weight-related conditions.
- Patients using pharmacotherapy should concomitantly pursue intensive lifestyle interventions, as this approximately doubles weight loss^{7, 8} and the use of other tool-box approaches (meal replacements, structured diets, structured behavioral modification techniques such as food and exercise diaries) as useful adjuncts to aid weight loss.

The Obesity Society urges the FDA to approve safe and effective medications for obesity management. Such safe and effective medications should be eligible for reimbursement by third party insurers.

The Obesity Society is the leading scientific society dedicated to the study of obesity. The Obesity Society is committed to encouraging research on the causes, treatment, and prevention of obesity as well as to keeping the scientific community and public informed of new advances in the field. For more information, please visit www.obesity.org.

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